



caBIG

cancer Biomedical
Informatics Grid



Cancer Biomedical Informatics Grid (caBIG) Working Group Charter

Version 1.0

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Working Group:

Special Interest Group:

Document Number:

Standard Operating Procedures

CTMS Best Practices

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SOP Working Group Charter

Document Change Record

Version Number	Date	Description
0.1	09/26/2005	Initial Draft and it is discussed at the 1 st SOP meeting
0.2	10/21/2005	Edit membership table, updated Operation Procedure, add Attachment C
1.0	10/25/2005	Approved



SOP Working Group Charter

Approval

This charter is effective upon the date of approval and issuance. Any questions, comments, suggestions or requests for further information should be directed to Andrea Hwang or Jieping Li.

Date

SOP Working Group Charter

Purpose

The purpose of this charter is to establish the SOP Working Group under the guidance of the CTMS Best Practices SIG.

Background

The CTMS Best Practices SIG has determined that there is a need to establish standard SOPs and best practices that can be leveraged to support collaborative cancer research. These SOPs shall leverage industry best practices to comply with Title 21 regulations and ICH guidelines for good clinical practices.

This Working Group will continue the work initiated by the C3DS User Group in developing Standard Operating Procedures. The C3DS User Group developed 43 work products (18 SOPs, Procedures, workflows, guidelines & templates) to support clinical trials research during Year 1. The SOPs and accompanying documentation were designed and authored to be technology neutral and to assure the authenticity and veracity of data collected during clinical research trials

Objectives

- Review/discuss recommended SOP list and prioritization
- Reach consensus on new SOPs and new business processes to enable efficient use of clinical data management applications or activities eliminating or substantially reducing any SOP or business process revision at their individual sites
- Share best practice knowledge for the conduct of clinical trials, according to ICH Guidelines, Title 21 Regulations (including 21 CFR Part 11) and regulations concerning the requirements and controls around patient confidentiality, the Health Insurance Portability and Accountability Act (HIPAA)
- Facilitate the exchange of useful information on clinical research trials, enabling the sites to remediate risk.
- Serve as a source to define requirements for enhancements, implementation, ongoing support and maintenance, and training.

Scope and Applicability

This charter applies to all current and future personnel utilizing SOPs to perform clinical research under the caBIG™ umbrella.

This charter is subject to periodic revisions based on the progress made and lessons learned.

SOP Working Group Charter

Authority

The SOP Working Group is authorized to make decisions aiding the process of defining and developing business processes and SOPs. The SOP Working Group will ensure that the business processes and SOPs are relevant and acceptable for the needs of caBIG™ and the individual member sites.

SOPs will be developed and approved by the SOP Working Group. The approved SOPs will be posted for review and confirmation by the CTMS Best Practices SIG.

Any deviations or revisions to existing SOPs and Attachments will also be presented to the SOP Working Group. For SOPs, the Working Group will follow the SOP approval procedures outlined in this charter. For Attachments, the Working Group will review the proposed changes to ensure no conflict with existing SOPs and note the revision in the meeting minutes.

Membership and Responsibilities

Membership shall be open to all caBIG™ participants, however only the cancer sites may have voting privileges. When there is more than one representative from a particular site, the organization identifies one individual as its primary representative and the other individual as the alternate representative. While everyone will have the opportunity to discuss and review items put before the Working Group, only the primary representative, or their designated alternate, may vote on initiatives put before the Working Group.

Member	Responsibilities
Co-chairperson (caBIG-affiliated members)	<ul style="list-style-type: none"> • Provide strategic direction to the CTMS BP SIG and SOP WG • Ensure the CTMS BP SIG and SOP WG adhere to NIH and NCI Policies and guidelines • Approve agenda items (including meeting minutes) • Schedule and facilitate meetings • Bring the body to vote once the appropriate level of discussion on particular issues have been reached
SOP WG members	<ul style="list-style-type: none"> • Responsible for achieving group objectives • Approve SOP WG decisions • Approve meeting minutes • Review and provide input on the SOPs and processes developed to support the SOP Working Group operations by the agreed upon time frame • Review SOPs reported out by the SOP Working group; Approve SOPs for implementation by those adopting cancer center sites.
SOP WG Reporter	<ul style="list-style-type: none"> • Responsible for reporting and updating SOP WG activities to the BP SIG • Track and maintain SOP revision log file

SOP Working Group Charter

Operating Procedures

1. The SOP Working Group will meet, at minimum, on a monthly basis, with special meetings called by the Co-Chairs, as needed.
2. An agenda for each SOP Working Group meeting will be prepared and sent out via listserv prior to the meeting date.
3. SOP Working Group members vote on key topics and issues related to the development and management of the standard operation procedures (SOPs) and business processes supporting clinical research operations.
4. The SOP Working Group is a consensus-driven body, where consensus is recognized as majority vote. Each voting member is allocated one vote. In the event of an impasse, the SOP Working Group Co-Chairs cast the deciding votes.
5. The SOP review procedure is illustrated in Attachment C. The SOP Working Group will vote and approve the SOPs. When SOPs are approved on Tuesday afternoon, it will be sent to the BP SIG for review on Thursday (same week – 4th week of the month); and SOP WG expect to receive the feedback from BP SIG before COB of the following Friday (1st week of the following month). Then, the revised version will be sent to the BP SIG before the BP SIG meeting (2nd Tuesday of the following month).
6. The meetings shall be conducted in accordance with Robert's Rules of Order, which are summarized in Appendix B.

SOP Working Group Charter

Appendix A: Working Group Members

Name	Primary (P) or Alternate (A)	Organization	Email Address	Phone Number
Yi-Cheng (Andrea) Hwang	P	Chao Family Comprehensive Cancer Center University of California, Irvine	ychwang@uci.edu	714-456-2226
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Lara Fournier	P	Oregon Health & Science University	fourniel@ohsu.edu	503-494-8446
Amy VanLeuvan		Mayo Clinic		
Sharon Elcombe		Mayo Clinic	elcombe@MAYO.EDU	
John Speakman	P	Memorial Sloan-Kettering Cancer Center	SpeakmaJ@MSKCC.ORG	
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Donna Marlatt	P	Dartmouth	donna.s.marlatt@DARTMOUTH.EDU	
Bob Annechiarico	P	Duke University	bob.annechiarico@DUKE.EDU	
Christo Andonyadis	A	NCI Director, Clinical Trials Development	andonyac@mail.nih.gov	301-402-6590
Doug Fridsma	P	University of Pittsburgh Medical Center		
Michele Pontinen		Booz Allen Hamilton	pontinen_michele@bah.com	484-432-9417
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Hadley White		Booz Allen Hamilton		
David Geismar		Booz Allen Hamilton		

SOP Working Group Charter

Appendix B: Introduction to Robert's Rules of Order¹

Robert's Rules of Order is a set of rules for conducting meetings, allowing everyone to be heard, while being able to make decisions without confusion. This methodology is a time-tested method of conducting business at meetings and public gatherings. It can be adapted to fit the needs of any organization.

Organizations using this procedure usually follow a fixed order of business. Below is a typical example:

1. Call to order
2. Roll call of members present
3. Reading of minutes of last meeting
4. Officers reports
5. Committee reports
6. Special orders --- Important business previously designated for consideration at this meeting
7. Unfinished business
8. New business
9. Announcements
10. Adjournment

Meeting participants engage in discussions or interact in the form of a moving motion – a proposal that the entire membership take action or a stand on an issue. Individual members can make a motion to: (1) call the group to order; (2) second a motion; (3) debate a motion; or (4) vote on a motion. There are four Basic Types of motions:

1. Main Motions: Introduce items to the membership for their consideration. They cannot be made when any other motion is on the floor, and yield to privileged, subsidiary, and incidental motions.
2. Subsidiary Motions: Change or affect how a main motion is handled. Subsidiary motions are voted on before the main motion.
3. Privileged Motions: Initiate items that are special or important matters unrelated to pending business.
4. Incidental Motions: Provide a means of questioning procedures concerning other motions and must be considered before the other motion.

How are Motions Presented?

1. Obtaining the floor:
 - a. Wait until the last speaker has finished
 - b. Address the Chairperson by saying, "Mr. (or Ms.) Chairperson"
 - c. Wait until the Chairperson recognizes you
2. Make your motion
 - a. Speak in a clear and concise manner
 - b. Always state a motion affirmatively. Say, "I move that we..." rather than, "I move that we do not..."
 - c. Avoid personalities and stay on your subject

¹ General Henry M. Robert, *Robert's Rules of Order* (1915). Public Domain.

SOP Working Group Charter

3. Wait for Someone to Second Your Motion
4. Another member will second your motion or the Chairperson will call for a second
5. If there is no second to your motion it is lost
6. The Chairperson states your motion
 - a. The Chairperson will say, "It has been moved and seconded that we..." placing your motion before the membership for consideration and action
 - b. The membership then either debates your motion, or may move directly to a vote
 - c. Once your motion is presented to the membership by the chairperson it becomes "assembly property", and cannot be changed by you without the consent of the members
7. Expanding on Your Motion
 - a. The time for you to speak in favor of your motion is now, rather than at the time you present it
 - b. The mover is always allowed to speak first
 - c. All comments and debate must be directed to the chairperson
 - d. Keep to the time limit for speaking that has been established
 - e. The mover may speak again only after other speakers are finished, unless called upon by the Chairperson
8. Putting the question to the membership
 - a. The Chairperson asks, "Are you ready to vote on the question?"
 - b. If there is no more discussion, a vote is taken
 - c. On a motion to move the previous question may be adapted

Voting on a Motion:

The method of vote on any motion depends on the situation and the by-laws of policy of your organization. There are five methods used to vote by most organizations, they are by:

1. Voice - The Chairperson asks those in favor to say, "aye", those opposed to say "no". Any member may move for an exact count.
2. Roll Call - Each member answers "yes" or "no" as his name is called. This method is used when a record of each person's vote is required.
3. General Consent - When a motion is not likely to be opposed, the Chairperson says, "If there is no objection..." The membership shows agreement by their silence, however if one member says, "I object," the item must be put to a vote.
4. Division - This is a slight verification of a voice vote where members raise their hand or stand. It does not require a count unless the chairperson so desires.
5. Ballot - Members write their vote on a slip of paper, this method is used when secrecy is desired

There are two other motions that are commonly used that relate to voting:

1. Motion to Table - This motion is often used in the attempt to "kill" a motion. The option is always present, however, to "take from the table", for reconsideration by the membership

SOP Working Group Charter

2. Motion to Postpone Indefinitely - Used as a means of parliamentary strategy to allow opponents of a motion to test their strength without an actual vote. Also, debate is once again open on the main motion

The aforementioned procedures are a sound way to conduct meetings; however, the process will only work if it is used properly:

1. Allow motions that are in order
2. Have members obtain the floor properly
3. Speak clearly and concisely
4. Obey the rules of debate
5. Most importantly, BE COURTEOUS

SOP Working Group Charter

Appendix C: SOP Review Procedure

